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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,919	06/29/2006	Jong Soo Woo	Q95721	1378

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EXAMINER	
CRAIGO, WILLIAM A	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,919	WOO ET AL.	
	Examiner	Art Unit	
	WILLIAM CRAIGO	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 August, 2010 has been entered.

Status of the Claims

Claims 1-8 are treated on the merits in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290 in view of Mukherji, US 6565877.

Woo is directed to non-crystalline cefuroxime axetil solid dispersions (title). Woo, examples, teaches a cefuroxime axetil granule comprising non-crystalline cefuroxime axetil (table 1 shows no heat absorption peak providing evidence the cefuroxime axetil is non- crystalline, a substantially amorphous form of cefuroxime axetil was also provided); tween 80 (a sucrose fatty acid ester), and cross-linked sodium carboxymethylcellulose (disintegrating agent). Col. 3, lines 51-58 of Woo lists water insoluble additives including microcrystalline cellulose, cross-linked polyvinylpyrrolidone, and cross-linked sodium carboxymethylcellulose. Page 5, line 11 of the instant application defines these ingredients as disintegrating agents. Therefore Woo teaches disintegrating agents as defined by applicant, see instant claims 1 and 2. Woo, examples 9-10 teaches the cefuroxime axetil granule further comprising a coating

materail and a pharmaceutically acceptable additive such as an enteric coat (compare instant claims 4-5.

Woo does not expressly teach a methacrylic acid-ethylacrylate polymer as instantly claimed which coats the cefuroxime axetil.

Mukherji is directed to taste masked compositions for bitter drugs, see col. 1, lines 5-9. Mukherji, example 1, teaches cefuroxime axetil in combination with a methacrylic acid-ethylacrylate copolymer (Eudragit L100-55, compare instant claims and applicant example 1) to produce granules of cefuroxime axetil which showed taste masking. Mukherji teaches the taste masking compositions effectively masks the taste of the drug without compromising the dissolution rate and allows formulation of liquid dosage forms which are suitable for children and elderly people; see col. 2, Lines 20-26 and col. 1, lines 13-31.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art elements of Woo with Mukherji to provide a cefuroxime axetil granule composition as claimed because Woo expressly teaches a non-cyrstalline cefuroxime axetil solid dispersion which provides high drug stability and bioavailability, and Mukherji expressly teaches a methacrylic acid-ethylacrylate copolymer improves cefuroxime axetil dosage forms by masking the bitterness of the drug. One of ordinary skill in the art would have been motivated to improve the composition of Woo in the manner taught by Mukherji to provide the combined benefits of improved drug stability and bioavailability in a taste masked formulation.

Mukherji, example 1, teaches a 1:1 ratio of polymer to drug; Woo, claim 2, teaches 0.01-0.5 parts by weight of surfactant, and 0.01-2 parts by weight of disintegrant based on 1 part by weight of the non-crystalline cefuroxime axetil (compare instant claim 3). Mukherji, col. 3, lines 36-46 teaches the granules may be further coated with enteric polymers to optimize taste masking; effectively masking the remaining bitterness (compare instant claims 4 and 5). Mukherji, co.l 3, lines 29-35, teaches the addition of pharmaceutically acceptable excipients such as flavoring agents (compare instant claim 4, pharmaceutically acceptable additive).

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, for example pharmaceutically acceptable flavoring agents can be added to the coating to provide an appealing flavor; coloring amounts can be added to provide an appealing color etc. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Accordingly, the subject matter of instant claims 1-6 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290 in view of Mukherji, US 6565877 as applied to claims 1-6 above, and further in view of James, US 4865851 A.

The teachings of Woo and Mukherji are discussed above. Woo and Mukherji teaches solution coating with spray drying (Mukherji) and suggests the step of pulverizing (example 1, Mukherji, teaches mixing the polymer and drug in a solution which is then dried and sized) because pulverizing is taken broadly to mean "to render into a dust or powder" as per its plain meaning. In Woo this is accomplished by spray drying the solution, in Mukherji the dried mass is "sized" to produce particles. The difference between the claimed method and the method as taught in Woo and Mukherji is that rather than dispersing the active agent in a solution of the polymer and sucrose fatty acid ester, the active agent is dispersed in a melt of the polymer and the sucrose fatty acid ester and subsequently cooled to produce the solid mass.

James is directed to taste masked cefuroxime axetil in particulate form (abstract). James teaches dispersing cefuroxime axetil in a molten lipid or mixture of lipids and atomizing the dispersion to provide particles having integral coatings and cooling and collecting the coated particles, see for example James, claim 13. James claim 14 teaches a melt temperature of 30 -80 degrees centigrade (compare instant claim 8).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings of Woo, Mukherji and James according to known methods to yield the predictable result of providing a method as instantly claimed because because Woo expressly teaches a non-cyrstalline

cefuroxime axetil solid dispersion which provides high drug stability and bioavailability, and Mukherji expressly teaches a methacrylic acid-ethylacrylate copolymer improves cefuroxime axetil dosage forms by masking the bitterness of the drug. The teachings of Woo and Mukherji expressly teaches the dispersion should be reduced to fine particles and James expressly teaches the steps of adding the cefuroxime axetil to a melt dispersion, cooling the mixture and atomizing (pulverizing) as instantly claimed. One of ordinary skill in the art would have been motivated to apply the teachings of James to Woo and Mukherji because James teaches the melt-dispersion steps result in an integral coating which is non-porous. The non-porous coating serves to reduce the bitterness (improve taste masking) and prevents cefuroxime axetil from coming into contact with aqueous media causing the cefuroxime axetil to gel (the gel form results in poor dissolution of the drug and hence lower bioavailability). Accordingly James teaches the melt dispersion technique helps solve the same problems Woo and Mukherji were solving.

Accordingly, the subject matter of instant claims 7-8 would have been prima facie obvious to one of ordinary skill at the time the invention was made, particularly in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is

(571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WILLIAM CRAIGO/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
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